IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*,

Plaintiffs,

and

State of Missouri, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. Food and Drug Administration, *et al.*,

Defendants,

and

Danco Laboratories, LLC,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

INTERVENOR-PLAINTIFFS' BRIEF IN RESPONSE TO GENBIOPRO'S MOTION FOR LEAVE TO INTERVENE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases Page(s)

Rules

Other Authorities

INTRODUCTION

Throughout the past two-and-a-half years, as this case has worked its way through the Fifth Circuit and U.S. Supreme Court twice, GenBioPro sat on the sidelines. Now, years later, GenBioPro wants to participate as a party, even though Danco and FDA have represented GenBioPro's interests throughout this litigation. This Court should deny the application for leave to intervene.

GenBioPro's application fails out of the starting gate for not including the required materials. Rule 24 requires an applicant in intervention to attach its own pleading to the motion. GenBioPro has not done so, and as a result, the application fails without even discussing the merits.

On the merits, GenBioPro knows it has a timeliness problem, but its attempt to evade that problem falls flat. GenBioPro insists that the States' challenge to the approval of the generic pill is substantially different than the private plaintiffs' initial challenge. Not so. GenBioPro insists the original challenge was based entirely on the private plaintiffs' attack on the 2000 approval of the abortion pill. But this Court already rejected that characterization. *All. for Hippocratic Med. v. FDA*, 668 F.Supp.3d 507, 556 (N.D. Tex. April 7, 2023). All the claims the States presently make about the 2019 approval were raised by the private plaintiffs in their original complaint. Indeed, the core of the States' claims with respect to the 2019 approval are nearly word-for-word identical to the challenge brought by the private plaintiffs.

FACTS

Plaintiff States and Danco both successfully moved to intervene, Danco three months after the complaint, and the States 11 months after the complaint—after factual developments threatened substantial harm on the States. ECF No. 33; ECF No. 175. The operative complaint is 199 pages, 788 paragraphs with nearly 2,600 pages of evidentiary materials, ECF No. 217, and the parties have briefed multiple sets of dispositive and non-dispositive motions.

Throughout the litigation, both original Plaintiffs and Plaintiff States challenged the FDA's approval of generic mifepristone. And contrary to Danco's assertion, the original Plaintiffs' challenge was *not* dependent on succeeding in challenging the 2000 mifepristone approval. Rather, the original Plaintiffs argued that even if they could not challenge the 2000 approval (*e.g.*, because of a statute-of-limitations issue), any reliance by FDA on the 2000 approval or 2016 Major Changes was arbitrary, capricious, and pretextual. ECF No. 1 at ¶¶ 382–89. Here, the States make the *exact same* arguments. ECF No. 217 at ¶¶ 763–67, 783–88.

GenBioPro's motion comes after FDA and Danco each moved to dismiss the Plaintiff States' amended complaint. ECF No. 218; ECF No. 221. FDA moved a mere two days before the Administration changed. After Plaintiff States responded to both motions to dismiss, ECF No. 228, the FDA moved this Court for a 60-day extension of time to file its reply to "ensure that the new Administration… is able to familiarize themselves with the issues in the case." ECF No. 238, at 2. But before the new Administration was "able to familiarize themselves with the issues," *id.*, it appears that line attorneys who worked on this case under the outgoing administration consented to GenBioPro's intervention, ECF No. 229, at 3. This Court granted FDA's request for a 60-day extension and permitted Danco's reply to be due the same day—May 5, 2025. ECF No. 241.

STANDARD OF REVIEW

To intervene as of right, "(1) the application for intervention must be timely; (2) the applicant must have an interest relating to the property or transaction which is the subject of the action; (3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest; and (4) the applicant's interest must be inadequately represented by the existing parties to the suit." *Guenther v. BP Ret. Accumulation Plan*, 50 F.4th 536, 542 (5th Cir. 2022) (quotation omitted).

In seeking to intervene permissively, GenBioPro must show that claims overlap with those of the parties to the suit and that allowing intervention will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(1)(B), (b)(3). The decision to deny permissive intervention is purely discretionary and is almost completely unreviewable on appeal. *See New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 471 (5th Cir. 1984) (en banc).

GenBioPro bears the burden of proof and persuasion on all issues. *See, e.g.*, *Guenther*, 50 F.4th at 542–43.

ARGUMENT

The application for leave to intervene should be denied for five reasons. *First*, the application is procedurally deficient. *Second,* the application is untimely. *Third*, FDA adequately represents GenBioPro's interests. *Fourth*, Danco adequately represents GenBioPro's interests. *Fifth*, GenBioPro's intervention at this stage would only serve to complicate this litigation.

I. The application for leave to intervene is procedurally deficient.

GenBioPro's application is deficient because it does not include a proper pleading under Rule 24(c). A putative intervenor must file "a pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c). "The requirements under Rule 24(c) are mandatory." *Brown v. Colegio de Abogados de Puerto Rico*, 277 F.R.D. 73, 76 (D.P.R. 2011). Failure to comply with Rule 24(c) warrants automatic denial of the motion. *See, e.g.*, *id.* at 76–77. Here, GenBioPro has attached a joinder of a motion to dismiss to its application, ECF No. 229-3, but that is insufficient. *See Abramson v. Pennwood Inv. Corp.*, 392 F.2d 759, 761 (2d Cir. 1968) (holding that potential intervenor-plaintiff's motion for leave to intervene was not accompanied

by a pleading even though he attached a copy of the plaintiff's complaint and stated that he wished to assert the same claims set forth therein).

This is particularly true where, as here, GenBioPro purports to reserve objections to venue. ECF No. 229 at p. 1. The law is crystal clear that intervention is consent to personal jurisdiction and venue. *See, e.g.*, *In re Bayshore Ford Trucks Sales, Inc.*, 471 F.3d 1233, 1248 (11th Cir. 2006) ("Westgate challenges the district court's jurisdiction over its person, but by filing a successful motion to intervene, it acquiesced to such jurisdiction."); *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 59 (D.D.C. 2003), *aff'd*, 362 F.3d 817 (D.C. Cir. 2004) ("DCH voluntarily intervened in this case, thus becoming a full participant in this lawsuit and assuming the risk that the Court could order relief against it…Accordingly, DCH cannot now be heard to object that the Court lacks jurisdiction over it or that venue is improper." (citations omitted)). GenBioPro's insistence otherwise, and its attempt to expressly reserve those defenses, will require GenBioPro to brief issues not included in the briefing already on file. Without filing an independent motion setting out its ostensibly unique arguments in favor of transferring venue, the application is procedurally inadequate.[1]

II. Genbiopro cannot intervene as of right.

GenBioPro's application should be denied for three reasons. *First*, the application is untimely. *Second*, the presumption of adequate representation by the government applies to this case, and GenBioPro cannot overcome it. *Third*, Danco adequately represents GenBioPro.

[1] To the extent that the joinder of the motion to dismiss could be construed as a motion to dismiss, it is inadequate. Dispositive motions in this District must be accompanied by a brief, and GenBioPro's "motion" does not include one. *See* L.R. 7.1(d), (h).

A. The application is untimely.

GenBioPro has not disputed that if their application is untimely, that is the end of their road. When determining whether intervention is timely, this Court analyzes four factors: "[1] the length of time the movant waited to file, [2] the prejudice to the existing parties from any delay, [3] the prejudice to the movant if intervention is denied, and [4] any unusual circumstances." *Rotstain v. Mendez*, 986 F.3d 931, 937 (5th Cir. 2021). GenBioPro fails on all fronts.

Timeliness. In the Fifth Circuit, courts determine whether an application is timely based on the "starting point" of the litigation, which is "either…the time the applicant knew…of his interest or from the time he became aware that his interest would no longer be protected by the existing parties to the suit." *Id.* (emphasis deleted). Here, in a case that has generated international media attention, GenBioPro had to have known of its interests in this litigation when it was first filed. That was in November 2022. GenBioPro waited two and a half years to file its application to intervene. Meanwhile, Danco, who is almost identically situated in interests to GenBioPro, intervened just a few months into the case. *See generally* ECF No. 20 at p. 4. The Fifth Circuit in *Rotstain* said waiting 18 months after learning the party's interests were at stake was too long. 986 F.3d at 938. GenBioPro waited almost twice as long.

GenBioPro disputes none of this. Instead, GenBioPro insists that the States' complaint raises issues "for the first time." ECF No. 229-1 at p. 4. Not so. The States raise the same arguments that the original Plaintiffs raised. Because GenBioPro's premise is demonstrably wrong, its conclusion falls as well.

GenBioPro errs first by misrepresenting the original complaint. It suggests that the original Plaintiffs admitted that their challenge to the 2019 generic approval would prevail only if they also prevailed on their challenge to the 2000 approval and that this was "their sole basis for seeking to vacate" the generic approval. *Id.* at 3, 7. That is doubly wrong, as this Court already determined.

First, the original Plaintiffs' challenge to the generic approval did *not* rest solely on their arguments about the 2000 approval. Rather, this Court said, "Plaintiffs argue the 2019 Approval was unlawful because FDA relied on the unlawful 2000 Approval *and* its unlawful 2016 Changes when approving generic mifepristone." *All. for Hippocratic Med.*, 668 F.Supp.3d at 556 (emphasis added). Second, the original Plaintiffs did not tie their challenge to the generic approval to the success of their challenge to the 2000 approval. Rather, they argued that even if they could not challenge the 2000 approval (such as because of a statute-of-limitations issue), it was still arbitrary, capricious, and pretextual for FDA to rely on that 2000 approval when issuing the 2019 approval. ECF No. 1 at ¶¶ 382–89. As this Court put it, their argument was that "FDA *relied* on the unlawful 2000 Approval," 668 F.Supp.3d at 556 (emphasis added)—reliance that was improper even if the underlying 2000 Approval could not be vacated.

The States raise the *exact same* arguments. Indeed, the core arguments are almost word-for-word identical. The original Plaintiffs pleaded FDA could not rely on the 2000 approval or the 2016 Major Changes, so FDA "lacked the clinical investigations, adequate testing, sufficient information, and substantial evidence to show the safety and effectiveness of mifepristone." ECF No. 1 at ¶ 385. Then those plaintiffs pleaded pretext: "FDA's illegal and unreasonable rationales for the 2019 ANDA Approval—in light of the political context of the agency's actions—indicate that the stated reasons for the 2019 ANDA Approval are pretext." *Id.* ¶ 388. Similarly, the States argue FDA could not rely on the 2000 approval or the 2016 Major Changes, so FDA "lacked the clinical investigations, adequate testing, sufficient information, and substantial evidence to show the safety and effectiveness of mifepristone." ECF No. 217 at ¶ 786. The States continue, ad-

vancing the same pretext argument: "FDA's illegal and unreasonable rationales for the 2019 Mifepristone Shared REMS Program and 2019 ANDA Approval—in light of the political context of the agency's actions—indicate that the stated reasons are pretext." *Id.* ¶ 765.

The only differences are twofold, neither of which changes the analysis. First, the States split the two arguments ([1] lack of scientific evidence and [2] pretext) into two counts rather than one. That of course makes no difference. Second, the States do not have a separate count challenging the underlying 2000 approval. That also makes no difference. Just like the original Plaintiffs did, the States still argue that the 2000 approval was improper and thus FDA is "[u]nable to rely on an unlawful approval." *Id.* ¶ 786. To be sure, the States are not seeking to vacate the 2000 approval. But the States are—like the original Plaintiffs did—arguing that the problems with that approval mean FDA could not rely on it 19 years later. That the States' complaint seeks *less* relief than the original Plaintiffs did (because the States do not seek to vacate the 2000 approval) does not give GenBioPro more reason to intervene. With respect to the generic approval, the States are asserting the *exact same* arguments the original Plaintiffs did.[2]

This Court can reject the intervention motion on this ground alone. GenBioPro's intervention motion rests entirely on its assertion that the nature of the challenge has changed substantially in ways that harm GenBioPro. Because that premise is fundamentally flawed, the intervention motion rests on nothing.

[2] Citing one of the Fifth Circuit decisions in this case, GenBioPro (at 7) points out that the original Plaintiffs argued that the 2000 approval and the 2019 Generic approval "impose the same injuries." What GenBioPro leaves out, is that this part of the Fifth Circuit's opinion comes from its analysis about standing. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 241 (5th Cir. 2023). As to the *merits*, just like the States do here, the original Plaintiffs argued on the merits that it was wrong for FDA to rely on the 2000 approval, even if the 2000 approval could not be independently challenged. ECF No. 1 at ¶¶ 382–89.

Prejudice to the existing parties. The prejudice inquiry focuses on the need to change deadlines or redo previous litigation. *Rotstain*, 986 F.3d at 938. Here, Plaintiff States face just that type of harm. The pending motions to dismiss have been almost completely briefed. If GenBioPro stands by its word and refuses to "acquiesce in venue in this District," ECF 229 at p. 1, then the parties are going to have to redo at least some of that briefing again. And GenBioPro stands to complicate that briefing because GenBioPro, who has purported to reserve its right to challenge venue, may have different waiver arguments than Danco, who intervened without purporting to reserve this right. Indeed, the whole point of the States filing a consolidated brief was to address all the arguments in the motions to dismiss at once. But now that GenBioPro is ostensibly going to challenge venue *again* despite having waived it, Plaintiff States will have to brief a new variant of the issue.

At the very least, if this Court permits intervention, it should require Danco and GenBioPro to file joint, consolidated briefs from here on out. The States already must respond to different briefs by two different parties. Adding a third to the mix will make briefing even more burdensome. The States have consistently consolidated their arguments—even though the interests vary somewhat between each State. Danco and GenBioPro can do the same.

Prejudice to GenBioPro. GenBioPro faces no prejudice from an inability to intervene. GenBioPro was happy for two years to have FDA and Danco represent its interests. Nothing has changed. As explained above, the States' challenge substantively is exactly the same as the original Plaintiffs' challenge.

Unusual circumstances. GenBioPro does not argue that there are unusual circumstances at issue in this case, and for good reason. Although this litigation is complex, nothing about this litigation is so unique as to warrant intervention at this late stage. *Compare Sierra Club v. Espy*,

18 F.3d 1202, 1205–06 (5th Cir. 1994) (intervention was timely after eight years of litigation because the intervenor's interests were first implicated seven years in).

B. FDA adequately represents GenBioPro.

In cases where an applicant tries to intervene on the same side as the government, "there is a presumption of adequate representation," and the applicant will be deemed inadequately represented "only upon a showing of adversity of interest, the representative's collusion with the opposing party, or nonfeasance by the representative." *Texas v. U.S. Dept. of Energy*, 754 F.2d 550, 553 (5th Cir. 1985); *see also* 7C Wright & Miller, *Federal Practice & Procedure* § 1909 (3d ed. June 2024 update).

Although this standard has not been heavily litigated in the Fifth Circuit, other courts (particularly the Eighth Circuit[3]) have developed a detailed framework for litigating applications for leave to intervene on the same side as the government.

As the Eighth Circuit has explained, GenBioPro can avoid the presumption of adequate representation only by showing (1) "that it stands to gain or lose from the litigation in a way different from the public at large," or (2) "that its interest is narrower and more parochial than the government's." *Entergy Arkansas, LLC v. Thomas*, 76 F.4th 1069, 1071–72 (8th Cir. 2023) (cleaned up). If the applicant cannot avoid the presumption, they must make "a strong showing" that the government "has committed misfeasance or nonfeasance in protecting the public." *North Dakota ex rel. Stenehjem v. United States*, 787 F.3d 918, 922 (8th Cir. 2015). Critically, an applicant cannot overcome the presumption of adequate representation simply because the government

[3] The Fifth Circuit has approvingly cited the Eighth Circuit's standard on this issue before. *See Hopwood v. Texas*, 21 F.3d 603, 605 (5th Cir. 1994).

refuses to defend a statute or because the applicant "disagree[s] with the" government's "litigation strategy or objectives." *Chiglo v. City of Preston*, 104 F.3d 185, 188 (8th Cir. 1997).

GenBioPro fails on all fronts.

First, GenBioPro does not stand to lose in the litigation any differently than the public at large. If FDA is forced to reinstate its previous safety requirements, that will affect the entire public at large. GenBioPro will not be uniquely affected.

Second, there is no narrower or more parochial interest at issue here. The Eighth Circuit has explained that this prong generally refers to an interest in real property. *See, e.g.*, *Mille Lacs Band of Chippewa Indians v. Minnesota*, 989 F.2d 994, 1000–01 (8th Cir. 1993). For example, in *Mille Lacs*, the court held that the representation was inadequate because applicants faced a depreciation in property values and/or a loss of the land entirely. *Id.* at 1001. But here, GenBioPro does not stand to lose any real property.

Third, GenBioPro cannot (and does not try to) show that there is misfeasance or nonfeasance in the representation of the public. Indeed, FDA moved to dismiss the Amended Complaint *two days* after leave to amend was granted. *See* ECF Nos. 218–19. And FDA took this case all the way to the Supreme Court when this Court first preliminarily enjoined the approval of mifepristone.

C. Danco adequately represents GenBioPro.

Where, as here, the applicant and the joined parties have the same ultimate objective in the lawsuit, then representation is inadequate only if it can demonstrate collusion, nonfeasance, or an adversity of interests. *Guenther*, 50 F.4th at 543. An applicant has the same ultimate objective as the joined parties when it ultimately wants the same outcome in the litigation. *See id.* at 543–45. Disagreeing on matters of litigation strategy is not enough. *See id.* at 543.

Here, GenBioPro and Danco have the same ultimate objective in the lawsuit: the boost in sales that comes when a pill can be distributed with fewer safeguards. GenBioPro was long content to have Danco represent GenBioPro's interests. And the nature of this lawsuit has not appreciably changed since then.

Indeed, GenBioPro has implicitly conceded that Danco adequately represents it. The non-compliant "responsive pleading" that GenBioPro has included in its application for leave to intervene "adopts, incorporates by reference, and joins in full the motions to dismiss filed by Defendants and Intervenor-Defendant Danco." ECF No. 229-3 at p. 1. If GenBioPro really thought that it had such unique interests at stake in this action, then surely it could have prepared its own brief in support of a motion to dismiss, raising the arguments that it deemed necessary to protect its interests.

GenBioPro relies (ECF No. 229-1 at p. 12) on the fact that Danco is its commercial competitor, but Danco also has an interest in approval of a generic drug. Pharmaceutical companies often manufacture both name-brand and generic drugs, knowing that different customers prefer different things. *FDA Ensures Equivalence of Generic Drugs*, U.S. Food and Drug Administration (Aug. 2002) (recognizing that more cost-conscience consumers often choose generic drugs, while other consumers regularly believe brand-name drugs are "better quality").[4] Danco has the ability to manufacture and market a generic version of mifepristone, so Danco's interests are just as strong as GenBioPro's.

[4] https://www.forwardhealth.wi.gov/WIPortal/content/provider/pac/pdf/FDAEnsuresEquivalence.pdf.spage

III. GenBioPro should not be allowed to intervene permissively.

GenBioPro admits (at 14) that timeliness is assessed more strictly when moving for permissive intervention. Because GenBioPro's arguments fail under mandatory intervention, it follows even more clearly that they fail with respect to permissive intervention.

Conclusion

The application for leave to intervene should be denied.

Dated: March 18, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with Local Rule 7.2 in that the brief does not exceed 25 pages (it is 12 pages), excluding the cover, tables, signature block, and certificates.

/s/ Joshua M. Divine

CERTIFICATE OF SERVICE

I hereby certify that, on March 18, 2025 the foregoing was filed electronically through the Court's electronic filing system and served by email on all parties.

/s/ Joshua M. Divine